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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:
David J. Zahniser, et al
Serial No.: 10/726,336
Filed: December 1, 2003
For: CYTOLOGICAL IMAGING SYSTEM AND METHOD

Group Art Unit: 2877
Confirmation No.: 5486
Examiner: Gordon J. Stock, Jr.

DECLARATION OF DAVID J. ZAHNISER UNDER 37 CFR § 1.132

I, David J. Zahniser, declare that:

1. I am a U.S. citizen and a resident of Wellesley, Massachusetts.

2. I am the President of Diagnostic Vision Corporation of Wellesley, Massachusetts.

3. I am also a consultant for Cytyc Corporation, which is the assignee of the above-referenced patent application entitled, "Cytological Imaging System and Method" (hereinafter "present application"), of which I am a named inventor.

4. I was employed by Cytyc Corporation from February 1989 - April 2002. My last position at Cytyc was as Vice President for Scientific Affairs.

5. My past and current responsibilities at Cytyc include the development of automated microscopy systems including hardware and software design. While at Cytyc, I worked with others to develop the use of light emitting diodes (LEDs) as an illumination source for an automated microscopy system. I currently have a grant from the National Institutes of Health to further develop the use of LEDs in microscopes.

6. I received a BS in physics from MIT in 1973 and an MS in physics from MIT in 1975. I have also received a PhD in BioPhysics from the University of Nijmegen in The Netherlands in 1979.

7. I have worked with the design of optical instruments for 33 years and, in addition, I have worked on the design of lighting systems for optical instruments using LEDs for 7 years.

8. The present application discloses, among other things, a solution to the problem of finding alternative light sources for optical instruments, such as microscopes.

9. By way of background, a particularly troublesome aspect of commercially available optical instruments, such as microscopes, is the illumination source. Tungsten and tungsten halogen lamps, which are the illumination source used in most routine clinical microscopes, degrade over their lifetime and must be replaced frequently. For example, as the hours of use on a tungsten lamp accumulate, the tungsten filament evaporates, causing its resistance to increase. To maintain a constant illumination output, the power to the bulb must be increased as the resistance in the filament increases. Increased power to the bulb, however, leads to an increase in filament temperature and a concomitant shift in the bulb's output spectrum. Furthermore, tungsten filaments evaporate more rapidly at higher temperatures. Lifetime is somewhat extended in a tungsten halogen lamp since the halogen reacts with the tungsten to form a compound that migrates back to the filament when the temperature of the lamp wall is sufficiently high. Even so, the filament in a tungsten halogen bulb gradually becomes thinner, giving rise to the same problems encountered with tungsten lamps.

10. In fluorescent microscopy, narrow band spectral filters are required to separate the excitation wavelengths from the emission wavelengths. This leads to the need for a more intense light source such as an arc lamp. For clinical microscopes, a Mercury arc lamp is typically used. Mercury lamps, however, have short lifetimes of only 50-400 hours. Mercury lamps are also extremely inefficient, since only a narrow range of wavelengths is used for fluorochrome excitation, while the lamp produces light over a broad spectrum of wavelengths, much of which is filtered out. In addition, mercury lamps are expensive, and hazardous due to the toxicity of mercury.

11. The present application discloses and describes the use of LEDs and LED arrays as novel substitutes for conventional microscope bulbs. The light source in an LED comes from a tiny cube of semiconductor material called a "die." Because dies are very small, optically coupling the LED output from a spatially small die or die array into a microscope condensor can be quite efficient. For example, to achieve 100mW of optical power in the slide plane, an electrical input power of about only about 2.5W is required, for an overall efficiency of about 4%. This is 4.8 to 100 times more efficient than conventional light sources. In addition, since the bandwidth of an LED is typically between 12 and 30 nm, the LED type may be chosen to match the required spectrum so that little or no filtering is needed.

12. Additional benefits of using LEDs as the light source in optical instruments, such as microscopes, include: LEDs are extremely bright; the brightness of an LED array can be adjusted with little change in color temperature; LEDs have extremely long lifetimes of approximately seven years; the light levels produced by an LED, and its on/off cycles, can be carefully controlled; LEDs can be manufactured with great accuracy at reasonable cost; and LEDs are inherently safe.

13. Aside from disclosing the benefits of using LEDs as the light source in optical instruments, the present application also discloses embodiments for using LEDs for use in such optical instruments.

14. I have thoroughly reviewed U.S. Patent No. 6,122,042 ("Wunderman"), and I have a clear understanding of its teachings. Wunderman presents a solution to the problem of analyzing and/or identifying the properties of material objects using *reflected* light. Wunderman does not, however, disclose a solution to the problem of finding alternative means of illumination for an optical instrument such as a microscope.

15. The problem of analyzing and/or identifying the properties of material objects using reflected light is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope. This is true, among other reasons, because the optics present in an optical instrument such as a microscope create spatial and operational constraints on the light source that are distinct from any of the light source constraints that may have been present in Wunderman.

16. Wunderman's failure to refer to Kohler illumination, or the use of microscope slides, illustrate the fact that the Wunderman patent is directed to a problem that is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope.

17. Because the spatial constraints placed upon the light source of an optical instrument such as a microscope differ from any of the light source constraints that may be present in the embodiments disclosed in Wunderman, even if I were looking for a reference that could provide guidance on how to solve the specific problem of using LEDs as the illumination source in an optical instrument, Wunderman would not commend itself to my attention, nor would it provide any useful insight.

18. Because the problem solved by Wunderman is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope, I do not even consider the Wunderman reference as being in the same field of endeavor as the subject matter of the present application.

19. Furthermore, because Wunderman presents a solution to the conceptually distinct problem of analyzing and/or identifying the properties of material objects using reflected light. Wunderman does not suggest, either explicitly or inherently, that one could arrive at the claims of the present application by simply adding a lens.

20. I have also thoroughly reviewed U.S. Patent No. 5,791,345 ("Ishihara"), and I have a clear understanding of its teachings. Ishihara presents a solution to the problem of analyzing blood in a non-invasive manner using *reflected* light. Like Wunderman, Ishihara does not disclose a solution to the problem of finding alternative means of illumination for an optical instrument such as a microscope.

21. The problem of analyzing blood in a non-invasive manner using reflected light is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope. This is true, among other reasons, because the optics present in an optical instrument such as a microscope create constraints on the dimensions of the light

source that are distinct from any of the light source constraints that may have been present in the Ishihara disclosure.

22. As with Wunderman, Ishihara's failure to refer to Kohler illumination or the use of microscope slides emphasizes the fact that Ishihara is directed to a problem that is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope. In fact, it would be impossible to analyze blood in a non-invasive manner using an optical instrument such as one that uses Kohler illumination and/or microscope slides.

23. Because the problem solved by Ishihara is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope, I do not consider Ishihara as being in the same field of endeavor as the present application.

24. Furthermore, because the spatial constraints placed upon the light source of an optical instrument such as a microscope differ from any of the light source constraints that may have been present in Ishihara, even if I were looking for a reference that could provide guidance on how to solve the specific problem of using LEDs as the illumination source in an optical instrument, Ishihara is not one that would commend itself to my attention.

25. Finally, because Ishihara presents a solution to the conceptually distinct problem of analyzing blood in a non-invasive manner using reflected light, Ishihara does not suggest, either explicitly or inherently, that one could arrive at the claims of the present application by simply adding a lens.

26. I have also thoroughly reviewed U.S. Patent No. 4,774,434 ("Bennion"), and I have a clear understanding of its teachings. Bennion presents a solution to the problem of mounting LED-based light displays on clothing. Bennion does not, however, disclose a solution to the problem of finding alternative means of illumination for an optical instrument such as a microscope. Nor does Bennion disclose a solution to either the problem of analyzing and/or identifying the properties of material objects using reflected light (as in Wunderman), or the problem of analyzing blood in a non-invasive manner using reflected light (as in Ishihara).

27. The problem of adapting LED circuits for use on clothing is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope. This is true, among other reasons, because the optics present in an optical instrument such as a microscope create spatial and operational constraints on the light source that are distinct from any of the light source constraints that may have been present in Bennion.

28. Because the problem solved by Bennion is conceptually distinct from the problem of finding alternative means of illumination for an optical instrument such as a microscope, I do not consider Bennion as being in the same field of endeavor as the above-referenced patent application.

29. Because the spatial constraints placed upon the light source of an optical instrument such as a microscope differ from any of the light source constraints that may have been present in Bennion, even if I were looking for a reference that could provide guidance on how to solve the

specific problem of using LEDs as the illumination source in an optical instrument, Bennion is not one that would commend itself to my attention.

30. Moreover, because Bennion presents a solution to the conceptually distinct problem of mounting LED-based light displays on clothing, Bennion does not suggest, either explicitly or inherently, that one could arrive at the claims of the present application by simply adding or otherwise using a lens with the apparatus disclosed Wunderman, Ishihara, or their combination.

31. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 12/19/05

David J. Zahniser